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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,779	06/21/2001	Chandran R. Sabanayagam	701586/50113-C	6933
50607	7590	10/31/2005	EXAMINER	
RONALD I. EISENSTEIN 100 SUMMER STREET NIXON PEABODY LLP BOSTON, MA 02110			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/886,779	Applicant(s) SABANAYAGAM ET AL.	
	Examiner Frank W Lu	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/1/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on August 3, 2005 has been entered. The claims pending in this application are claims 11 and 23-38. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on August 3, 2005.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11 and 23-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 11 and 23 recites the limitation "the growth strand" in d) of the claims. There is insufficient antecedent basis for this limitation in the claim. Please clarify.

5. Claim 23 is rejected as vague and indefinite in view of the phrase "each extended immobilized oligonucleotide comprises at least two copies extending at the terminus in the z-dimension" in d) of the claim because it is unclear how a dimension (ie., z dimension) has a terminus. Please clarify.

6. Claim 30 is rejected as vague and indefinite in view of the phrase "each extended immobilized oligonucleotide comprises at least two copies of said sequence of interest such that

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the array has redundancy in the terminus of the z-dimension” because it is unclear how a dimension (ie., z dimension) has a terminus. Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 11 and 23-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.*, (US Patent No. 5,753,439, filed on May 19, 2003).

Smith *et al.*, teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about 10,000 different probes that hybridize with target nucleic acid with multiple repeats (see column 9, lines 18-34 and column 12, and Figure 5F). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1 and 2).

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Regarding claims 11 and 23, since claims 11 and 23 are directed to a product (an ordered array of immobilized oligonucleotides) and are not directed to a method, the method steps recited in claims 11 and 23 which are used to make the ordered array of immobilized oligonucleotides are no patentable weight and claims 11 and 23 are product-by-process claims. Note that it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Since claims 11 and 23 are directed an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest extending in the z dimension while Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats that hybridize with target nucleic acids that have the same number of or more repeats than the probes (see column 9, lines 18-34, column 12, column 15, claims 1 and 2 and Figure 5 F with the examiner's handwritings in the previous office action), Smith *et al.*, disclose an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) is attached to the array by its 5' end on a position by its x and y coordinates and comprises at least two copies of sequence of interest (ie., repeats) as recited in claims 11 and 23. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to

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another end has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claim 30, claim 30 is directed an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate and each sequence of interest is different for each extended immobilized oligonucleotide. Since Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats that hybridize with target nucleic acids that have the same number of or more repeats than the probes wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34, column 12, and column 15, claims 1 and 2 and Figure 5F with the examiner's handwritings in previous office), Smith *et al.*, teach an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., repeats) and each sequence of interest (ie., each of repeat sequences) is different and can bind to a different target nucleic acid as recited in claim 30. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claims 24-29 and 31-33, since these different probes taught by Smith *et al.*, have 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), claims 24-29 and 31-33 are anticipated by Smith *et al.*.

Regarding claims 34-38, different probes on the arrays in Figures 6A to 6C taught by Smith *et al.*, have 10-109 repeats wherein 5' and 3' ends of these probes are labeled with biotin and rhodamine respectively. Target nucleic acids comprising 88, 55, and 17 repeats with a fluorescein at their 3' ends are hybridized with an identical array in separate experiments and digested with S1 nuclease. Then strand displacement assays are performed. When the probe contains more internal repeats than the target, the rhodamine label is lost in the strand displacement and the resultant product is red. Similarly, when the target contains more internal repeats than the probe, the fluorescein label is lost and the product is green. When the probe and the target both contain the same number of repeats, both rhodamine and fluorescein remain and the resultant color is yellow (see column 12, example 4, and Figures 6A to 6C). When target nucleic acids comprising 88, 55, and 17 repeats hybridize with their corresponding probes (having 88, 55, and 17 repeats) on the array, the resultant colors must be yellow. Therefore, Smith *et al.*, teach that at least two copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claims 34 and 35, at least ten copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 37, and at least fifty copies of a fragment of a template nucleic acid (ie., 88 or 55 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeat of the probes on the array) are

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hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 38.

Therefore, Smith *et al.*, teach all limitations recited in claims 11 and 23-38.

Response to Arguments

In page 8, fifth paragraph bridging to page 10, second paragraph of applicant's remarks, applicant argues that Smith *et al.*, do not teach "the **3' ends of the final**, extended oligonucleotides of the claimed **arrays are highly variable**" because "the 5' and 3' ends of Smith arrays are constant. The internal region is variable".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Although the methods recited in claims 11 and 23 may have an ability to produce extended oligonucleotides with highly variable 3' end, the claims do not require that "**3' ends of the final**, extended oligonucleotides of the claimed **arrays are highly variable**" as argued by applicant. Furthermore, the claims are directed to products and are not directed to methods. Note that it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 11 and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,284,497 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but examined claims in this instant application are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although independent claims 11 and 23 in this instant application are directed to an array while claim 1 of U.S. Patent No. 6,284,497 B1 is directed to a method of generating an array, claim 1 of U.S. Patent No. 6,284,497 B1 teach or contain an array recited in claim 11 or claim 23 in this instant application. Therefore, claims 11 and 23 in this instant application are anticipated by claim 1 of U.S. Patent No. 6,284,497 B1.

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Response to Arguments

In page 10, third and fourth paragraphs of applicant's remarks, applicant argues that "[A]pplicant will file an executed terminal disclaimer separately".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because applicant has not filed a terminal disclaimer yet.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

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(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
Primary Examiner
October 24, 2005

